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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Denis MARTIN et al.

Serial No.: 10/650,123

Group Art Unit: 1645

Filed: August 28, 2003

Examiner: Jennifer E. GRASER

For: PHARMACEUTICAL COMPOSITIONS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
  - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - a notice of allowance under 37 C.F.R. § 1.311; and

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is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

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- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

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Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☒ Copies of materials listed but not attached were cited in an international search report dated March 5, 2004.
- ☐ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached (except for the foregoing).

### Non-English Language References

- ☒ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
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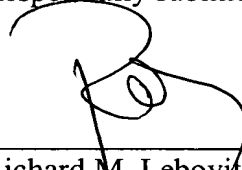
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- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: IDB-0033

Date: January 13, 2006

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

### Complete if Known

Application Number	10/650,123
Filing Date	August 28, 2003
First Named Inventor	Denis MARTIN et al.
Group Art Unit	1645
Examiner Name	Jennifer E. GRASER
Attorney Docket Number	IDB-0033

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	3	Martin et al.; "Highly Conserved <i>Neisseria meningitidis</i> Surface Protein Confers Protection against Experimental Infection," J. Exp. Med, 7 April 1997, pages 1173-1183, Vol. 185, no. 7.	
	4	Martin et al. "Candidate <i>Neisseria meningitidis</i> NspA vaccine," Journal of Biotechnology, 83 (2000) 27-31.	
	5	Carmenate et al.; Recombinant Opc protein from <i>Neisseria meningitidis</i> reconstituted into liposomes elicits opsonic antibodies following immunization; Biotechnol. Appl Biochem (2001) 34, 63-69	
	6	Christodoulides et al.; Immunization with recombinant class 1 outer-membrane protein from <i>Neisseria meningitidis</i> : influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci; Microbiology (1998) 144, 3027-3037; XP-002271046	
	7	Martin et al.; Recombinant NspA incorporated into liposomal vesicles induces functional antibodies; Vaccine Research Unit, Laval University Medical Center, Ste-Foy, Quebec, Canada	
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	9	Tinsley et al.; Antibodies recognizing a variety of different structural motifs on meningococcal Lip antigen fail to demonstrate bactericidal activity; Journal of General Microbiology (1992), 138, 2321-2328	
	10	Moe et al.; Functional Activity of Anti-Neisserial Surface Protein A Monoclonal Antibodies against Strains of <i>Neisseria meningitidis</i> Serogroup B; Infection and Immunity, June 2001, pp. 3762-3771	
	11	Hou et al.; Conformational Epitopes Recognized by Protective Anti-Neisserial Surface Protein A Antibodies; Infection and Immunity, Dec. 2003, pp. 6844-6849, vol. 71, no. 12.	
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	13	Moe et al.; Sequential Immunization with Vesicles Prepared from Heterologous <i>Neisseria meningitidis</i> Strains Elicits Broadly Protective Serum Antibodies to Group B Strains; Infection and Immunity, Nov. 2002, p 6021-6031, vol. 70, no. 11.	
	14	Koroev et al., Induction of Antimeningitis Immunity by Synthetic Peptides: III. <sup>1</sup> Immunoactive Synthetic Fragments of the NspA Protein from <i>Neisseria meningitidis</i> ; Russian Journal of Bioorganic Chemistry, Vol. 28, No. 4, 2002, pp. 263-268	
	15	Arigita et al.; Restored functional immunogenicity of purified meningococcal PorA by incorporation into liposomes; Vaccine 21 (2003) 950-960	
	16	Wright et al.; Immunization with the Recombinant PorB Outer Membrane Protein Induces a Bactericidal Immune Response against <i>Neisseria meningitidis</i> ; Infection and Immunity, Aug. 2002, pp. 4028-4034, vol. 70, no. 8.	

17	Arigita et al.; Liposomal Meningococcal B Vaccination: Role of Dendritic Cell Targeting in the Development of a Protective Immune Response; Infection and Immunity, Sept. 2003, p. 5210-5218, vol. 71, no. 9.	
18	Jolley et al.; Immunization with Recombinant Opc Outer Membrane Protein from <i>Neisseria meningitidis</i> : Influence of Sequence Variation and Levels of Expression on the Bactericidal Immune Response against Meningococci; Infection and Immunity, June 2001, p. 3809-3916, vol. 69, no. 6.	
19	Idanpaan-Heikkila et al.; The antibody response to a prototype liposome vaccine containing <i>Neisseria meningitidis</i> outer membrane protein P1 produced in <i>Bacillus subtilis</i> ; Vaccine, Vol. 13, No. 16, pp. 1501-1508, 1995.	
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23	Morley et al.; Vaccine prevention of meningococcal disease, coming soon?; Vaccine 20 (2002) 666-687	
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25	Bethell et al.; Meningococcal vaccines; Expert Rev. vaccines, 1(1), 75-84 (2002)	
26	Rosenqvist et al.; The 5C Protein of <i>Neisseria meningitidis</i> Is Highly Immunogenic in Humans and Induces Bactericidal Antibodies; The Journal of Infectious Diseases 1993; 167:1065-73	

Examiner Signature		Date Considered	
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